

# Nanoform Management Presentation

Q1 2025

May 20<sup>th</sup>, 2025



# Disclaimer

## Forward-Looking Statements

This presentation contains forward-looking statements, including, without limitation, statements regarding Nanoform's strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this presentation are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation, including, without limitation, any related to Nanoform's business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other companies, and other risks described in the Report of the Board of Directors and Financial Statements for the year ended December 31, 2024 as well as our other past disclosures. Nanoform cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Nanoform disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this presentation represent Nanoform's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.





# Introduction & Key Business Highlights

CEO Edward Hæggström

# Key strategy

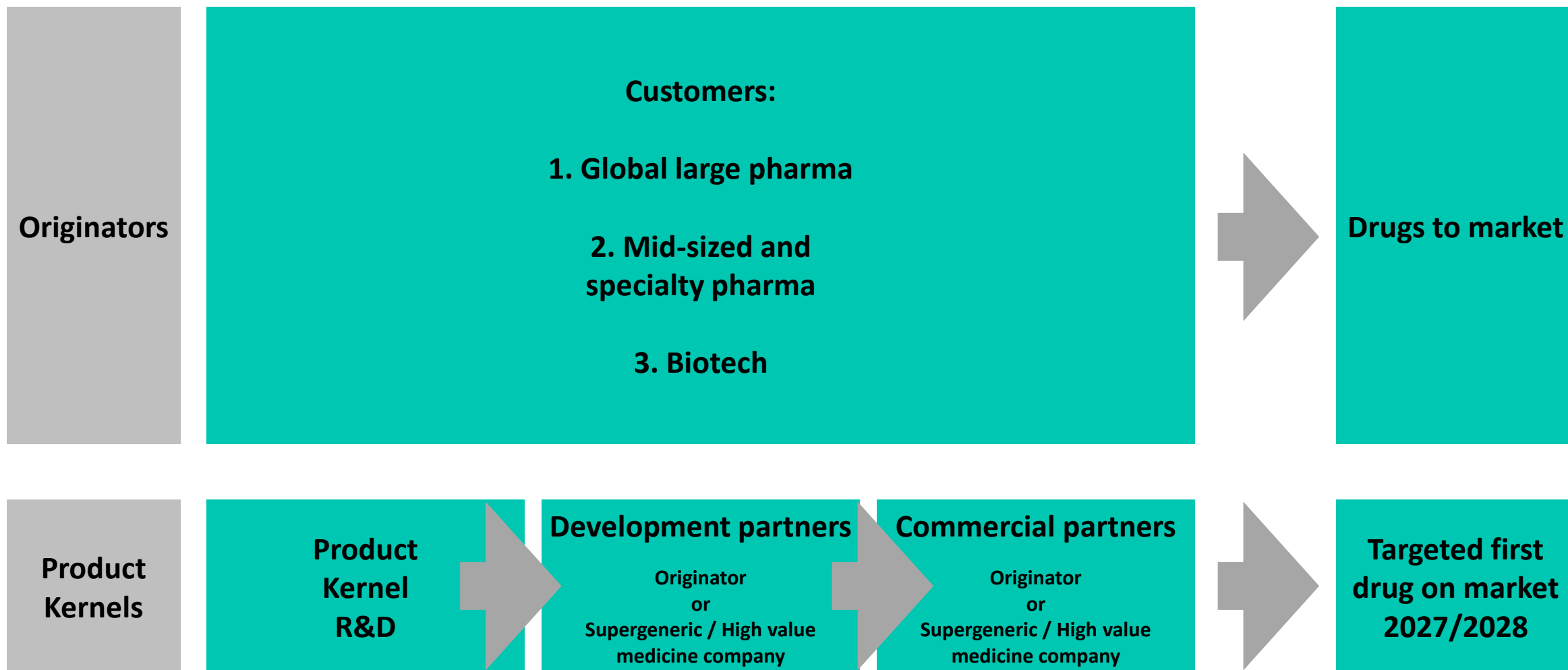
**All  
active pharmaceutical  
ingredients (API's)  
should be Starmapped (AI)**

**Nanoform work with  
customers/partners to  
enable novel & existing  
molecules to become new  
and improved medicines**

**In parallel, to show a  
conservative industry the  
power of nanoforming, we  
create up to a dozen  
'product kernels'**



# Nanoform Technology – route to market



# Proprietary technology platforms

## ***Small molecules***

Proven CESS®\* nanotechnology enables new medicines through *improved bioavailability, higher drug load & novel formulations*

[www.nanoform.com/en/technologies-and-services/small-molecules/](http://www.nanoform.com/en/technologies-and-services/small-molecules/)

## ***Large molecules***

Unique BIO nanoparticles enable improved routes of administration with *high drug load* and *long-acting delivery*

[www.nanoform.com/en/technologies-and-services/biologics/](http://www.nanoform.com/en/technologies-and-services/biologics/)

## ***Formulation***

Highly differentiated *novel formulations* and *unique drug delivery opportunities* drive optimized therapeutic potential & patient convenience

<http://www.nanoform.com/en/technologies-and-services/formulation/>

## ***AI***

STARMAP® 2.0 online *picks best candidates* and *accelerates development* by integrating deep expertise with sparse data AI

<http://www.nanoform.com/en/technologies-and-services/starmap/>

# Nanoform key business highlights

**I**

**Full mosaic of many license and supply agreements emerge for our leading Product Kernels**

**II**

**Continued growth in new customers, new projects, revenue and other operating income**

**III**

**Successfully manufacturing 100kg of nanoenzalutamide, next up is pivotal clinical studies (final), with first read-out during summer**

**IV**

**Patent granted in USA for small molecule controlled crystallization platform that produces crystalline polymer embedded nanoparticles (cPENs™)**

**V**

**Nanoform continues on path to become a cost leader in the field of particle engineering**

**VI**

**We expect nanoenzalutamide to be the first nanoformed medicine to reach the market – with a planned launch in 2027/28 in the US/EU**

**VII**

**Company mid-term business targets 2030 to be announced during 2025 in conjunction with Capital Markets Day**





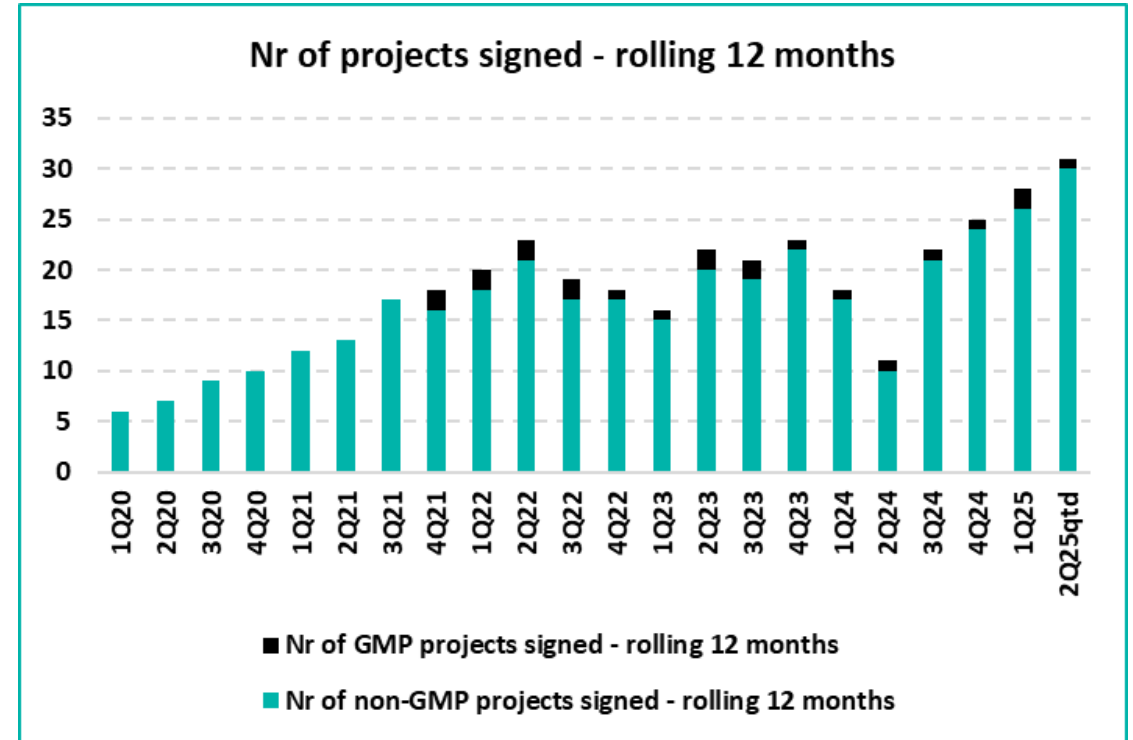
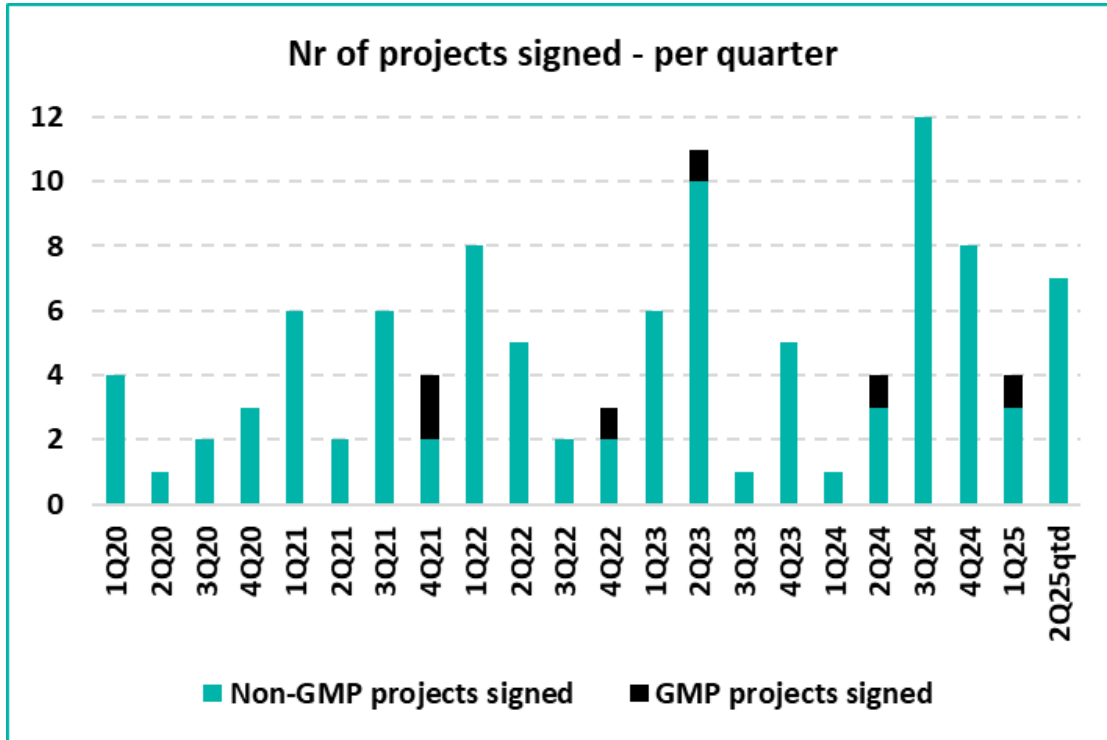


# Financials

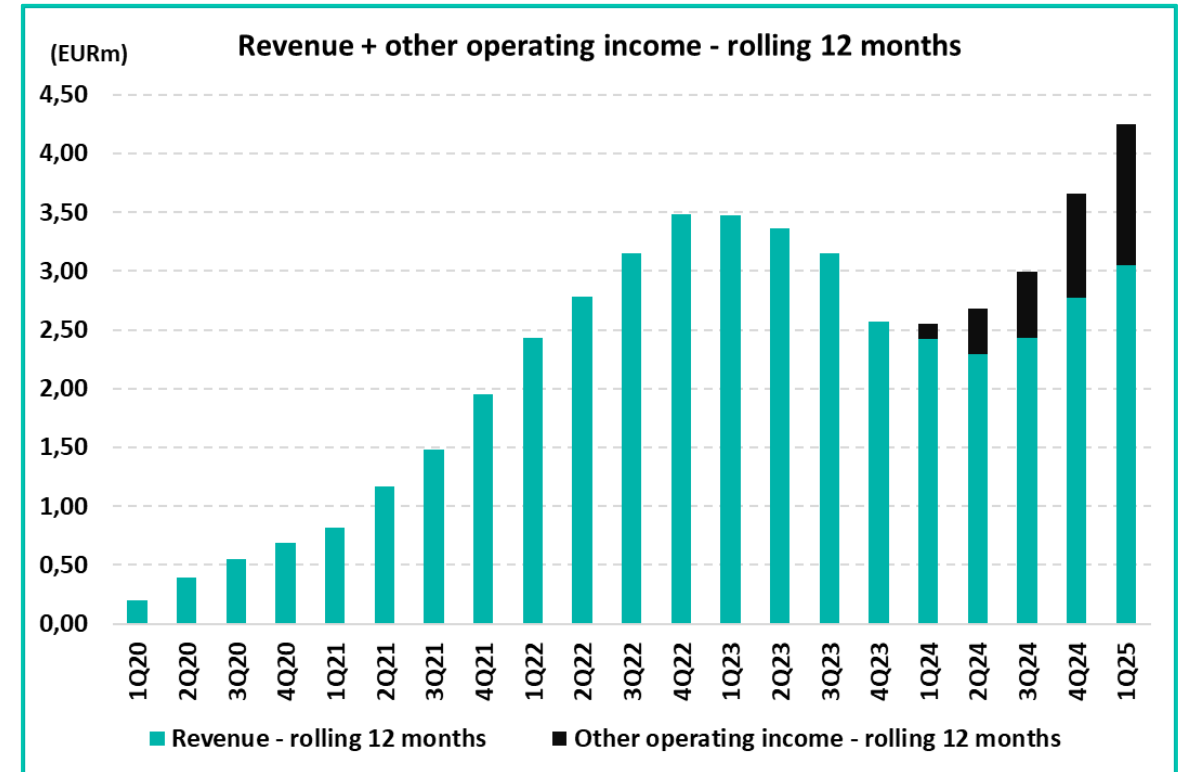
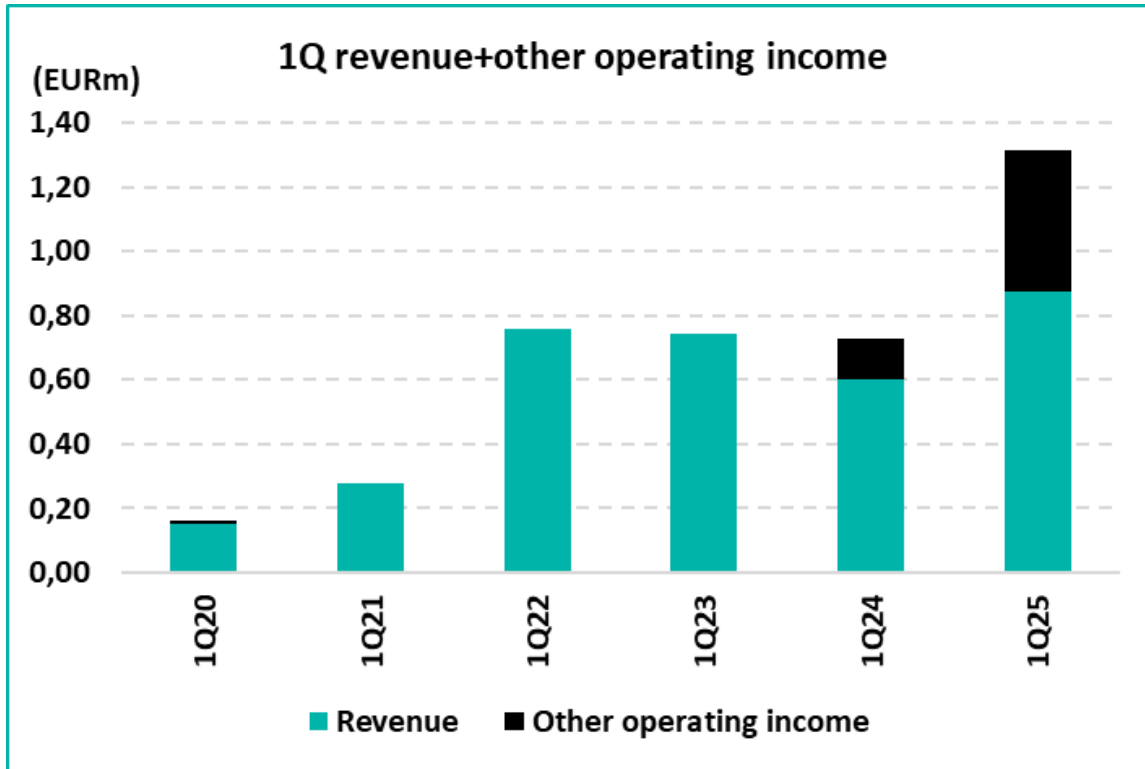
CFO Albert Hæggström



# Nr of projects signed – rolling 12 months at new record

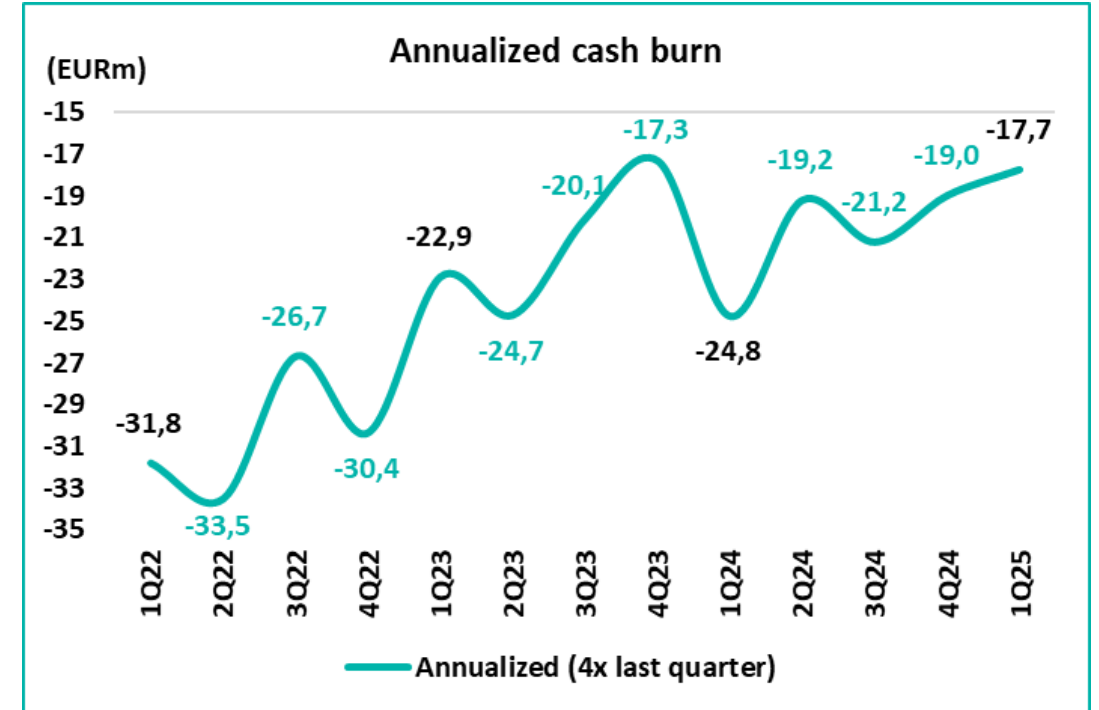
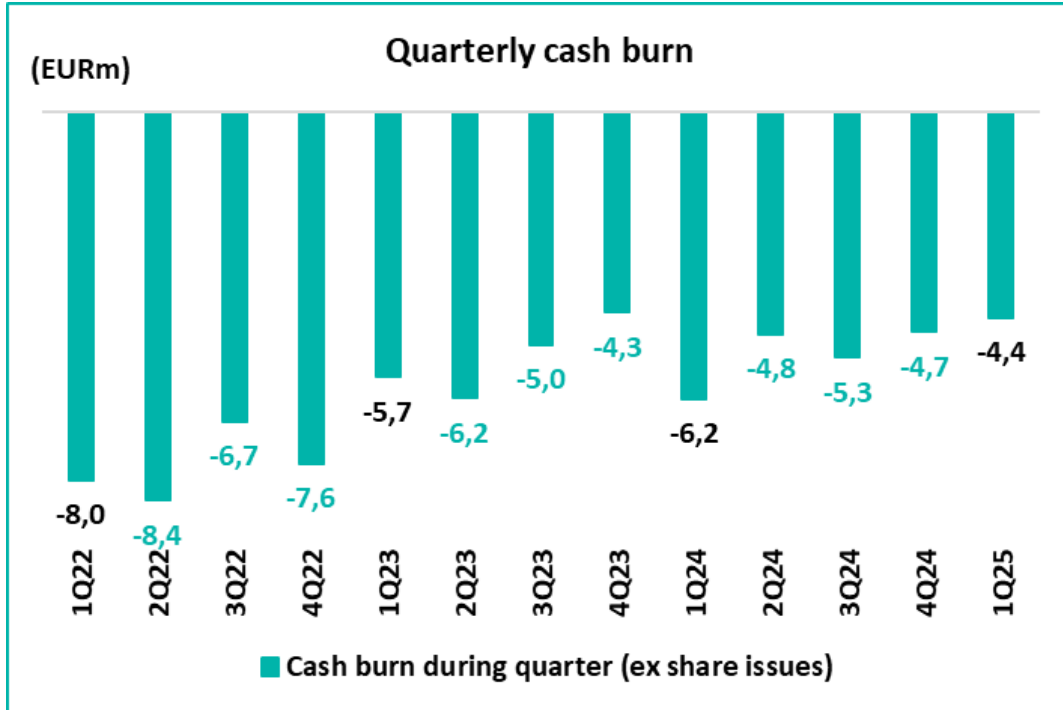


# Revenue +46% y/y in 1Q25 at the same time as other income also grew





# Improvement in cash flow to continue



At the end of 1Q25, Nanoform had more than EUR 37m in cash & short-term government bonds and no debt

# Dealmaking update on leading Product Kernels

## NANOENZALUTAMIDE\*

Germany	Term sheet agreed
France	Term sheet agreed
Japan	Term sheet agreed
US	Term sheet agreed
Spain	Term sheet negotiations ongoing
UK	Term sheet negotiations ongoing
Canada	Term sheet negotiations ongoing
Italy	Discussions initiated
Brazil	Discussions initiated
South Korea	Discussions initiated
Rest of EU	Discussions initiated
MENA	Discussions initiated
RoW	Discussions initiated

### Total financial potential of nanoenzalutamide project

- EUR 10m+ in potential development milestones 2025-2028
- EUR 25m+ in potential sales milestones after launch
- Some regions have profit share post launch between Nanoform+ONConcept consortium & commercialisation partners
- Market share estimates 10-30% => potentially 1000kg+ peak demand
- Supply price varies between markets and whether profit share or not

*\*Today Nanoform owns 25% of the nanoenzalutamide project*

## NANOAPALUTAMIDE\*\*

EU	Term sheet negotiations ongoing
US	Term sheet negotiations ongoing
Global	Term sheet negotiations ongoing

### Total financial potential of nanoapalutamide project

- Details to follow after term sheets/deals signed

*\*\*Today Nanoform owns 100% of the nanoapalutamide project*

## NANOENCORAFENIB\*\*\*

### Total financial potential of nanoencorafenib project

- Term sheets agreed with two specialist investors to invest EUR 3-5m into development of nanoencorafenib
- Investment will finance the clinical development up to commercialization of the kernel
- Pre-money valuation of nanoencorafenib kernel EUR 5m
- Nanoform can receive low-single-digit EUR million milestones and up-to-mid-single-digit %royalties
- Nanoform will own 40-50% of the project after investments by the two specialist investors

*\*\*\*Today Nanoform owns 100% of the nanoencorafenib project*

# Nanoform near-term business targets 2025 – all on track

**I**

**To sign several license/commercial supply agreements on several product kernels during 2025**

**II**

**First pivotal bioequivalence clinical study with a nanoformed medicine**

**III**

**Increased number of non-GMP and GMP projects signed in 2025 vs 2024**

**IV**

**Improved free cash flow in 2025 vs 2024**





# Commercial

CCO Christian Jones

&

CDO Peter Hänninen



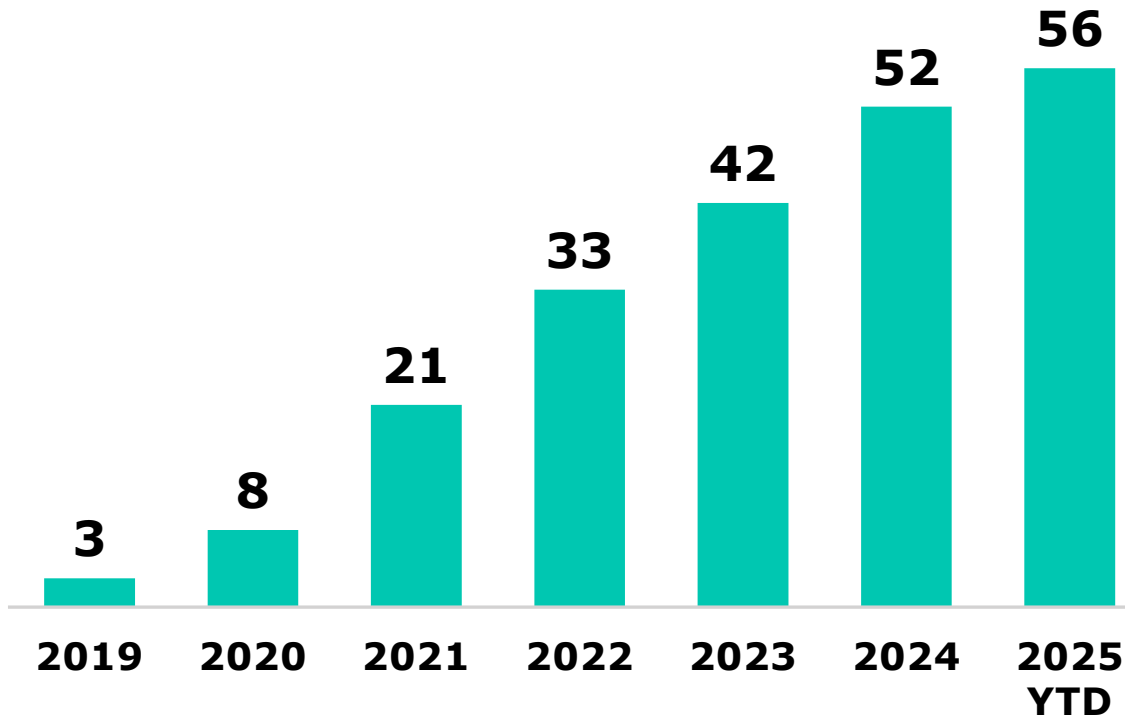
# Nanoform commercial highlights

I	Global pharma industry feedback - Nanoform's small/single pill strategy can enable significant commercial value
II	Strong large pharma interest in Nanoform's high drug load subcutaneous biologics platform
III	Continued growth in signed customers and projects
IV	New US global major pharma client signed
V	Takeda will present positive data on respiratory nanoformulations of their A1AT protein at the Drug Delivery Forum - Berlin June 3rd
VI	New grant from the Gates Foundation to work on multiple development projects
VII	Exclusive sales distribution agreement signed with CBC for Japan market

# Cumulative number of customers and customer projects signed

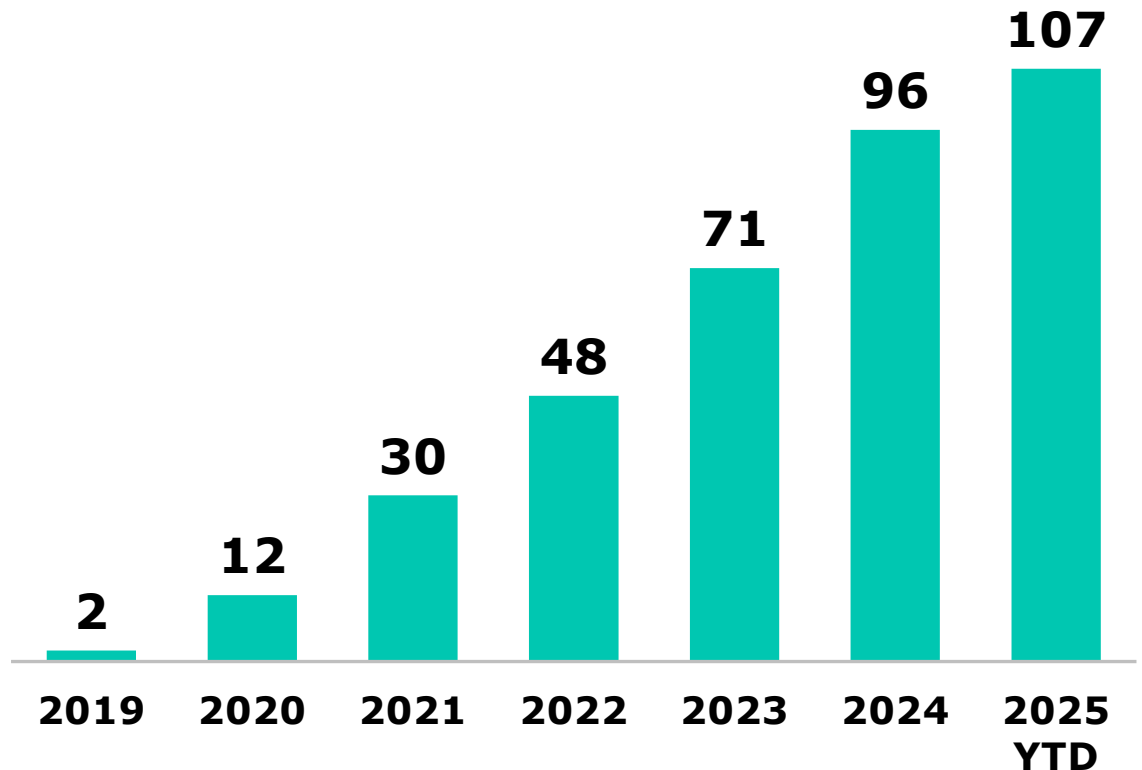
*Customers*

3 new in Q1  
and 4 YTD



*Customer Projects*

4 new in Q1  
and 11 YTD





# Commercial Relationships 2019 - Q1 2025

## Customer mix

**12**  
**major**  
**pharma**

**41**  
mid-sized,  
specialty  
pharma &  
biotech  
companies

## Selection of partners

Takeda



GSK



BILL & MELINDA  
GATES foundation



# Nanoform Product Kernel overview\*

Originator	Indication	Expected originator peak sales	Nanoform Product Kernels					Nanoform Pre-Clinical (non-GMP)				Nanoform Clinical (GMP)		Nanoform at Market
			Nanoformed API	Delivery route / dosage form	Nanoform ownership today	Development partnering status	Targeted commercial partnering	PoC*	Pre-formulation + in-vitro	Dosage form development + in vivo	PoP* / Dosage form development	Phase 1 / Pilot clinical trial	Pivotal - final - clinical trial	Targeted market launch
Astellas/Pfizer	XTANDI®/Prostate cancer	~\$5bln	Nanoenzalutamide	Oral / Tablet	25 %	OnConcept Consortium	2025						2025	2027 US & 2028 EU
Johnson & Johnson	ERLEADA®/Prostate cancer	~\$5bln	Nanoapalutamide	Oral / Tablet	100 %	Discussion ongoing	2025					2025-2026	2026-2027	2032 US & EU
Pfizer	BRAFTOVI®/Melanoma and colorectal cancer	~\$800mln	Nanoencorafenib	Oral / Tablet	100 %	Discussion ongoing	2025					2026	2027	2030 US & 2033 EU
Undisclosed	Inflammation		Undisclosed	Oral / Tablet	100 %	Partnered	2025							
Undisclosed	Oncology		Undisclosed	Oral / Tablet	100 %	2026	2027-28							
Undisclosed	Prostate cancer		Undisclosed	Long Acting	100 %	2025	2026-27							
Undisclosed	Oncology		Undisclosed	Long Acting	50 %	Partnered	2026							
Undisclosed	Oncology		Undisclosed	High Conc. Sub.Cut. Bio	100 %	2025	2026-27							
Undisclosed	Obesity		NanoGLP-1	Inhaled	100 %	2026	2027-28							

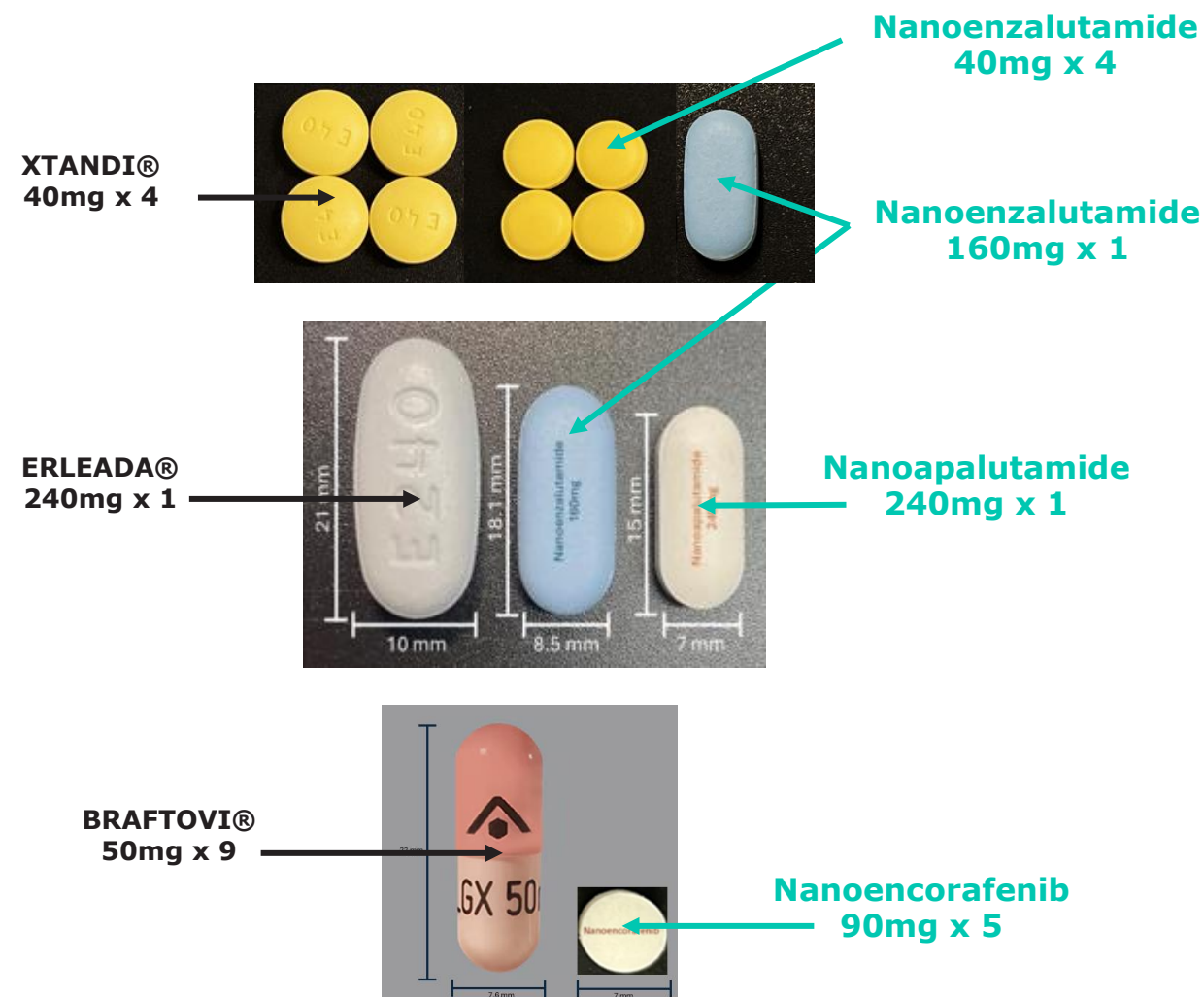
\*Only Product Kernel pipeline, i.e. not including customer projects

\*PoC = Proof of Concept

\*PoP = Proof of Process

# Small molecules – Nanoform enables small/single pill strategy

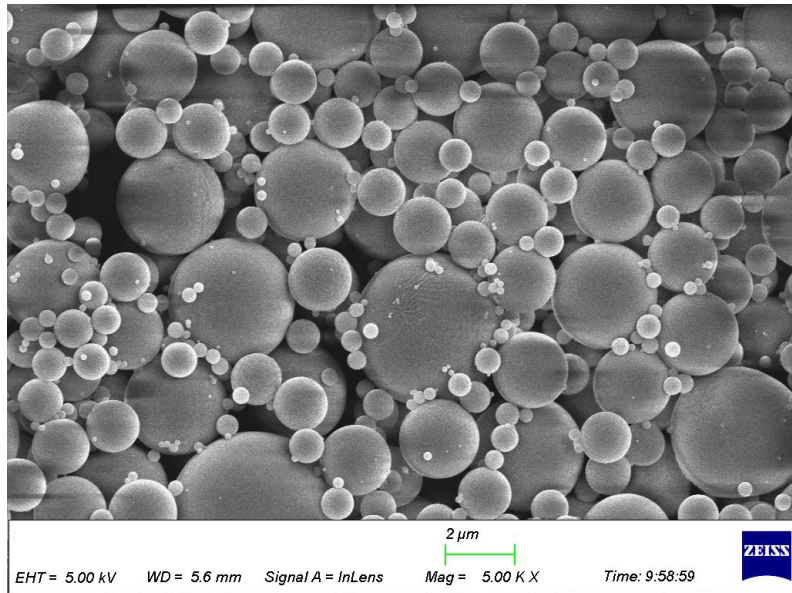
	Existing drug	Nanoformed version
	<b>XTANDI®</b>	<b>Nanoenzalutamide</b>
Formulation	ASD	Crystalline Nanoparticle
Drug load 160mg (x1)	-	40 %
Drug load 40mg (x4)	12 %	40 %
Size 160mg (x1)	-	18.1 x 8.6 mm
Size 40mg (x4)	10.1 mm	8.0 mm
	<b>ERLEADA®</b>	<b>Nanoapalutamide</b>
Formulation	ASD	Crystalline Nanoparticle
Drug load 240mg (x1)	21 %	42 %
Drug load 60mg (x4)	7 %	42 %
Size 240mg (x1)	21 x 10 mm	15 x 7 mm
Size 60mg (x4)	17 x 9 mm	8 mm
	<b>BRAFTOVI®</b>	<b>Nanoencorafenib</b>
Formulation	ASD	Crystalline Nanoparticle
Drug load 90mg (x5)	-	-
Drug load 75mg (x6)	12 %	-
Drug load 50mg (x9)	12 %	-
Drug load 45mg (x10)	-	-
Size 90mg (x5)	-	-
Size 75mg (x6)	23 x 8.5 mm	-
Size 50mg (x9)	22 x 7.6 mm	-
Size 45mg (x10)	-	-



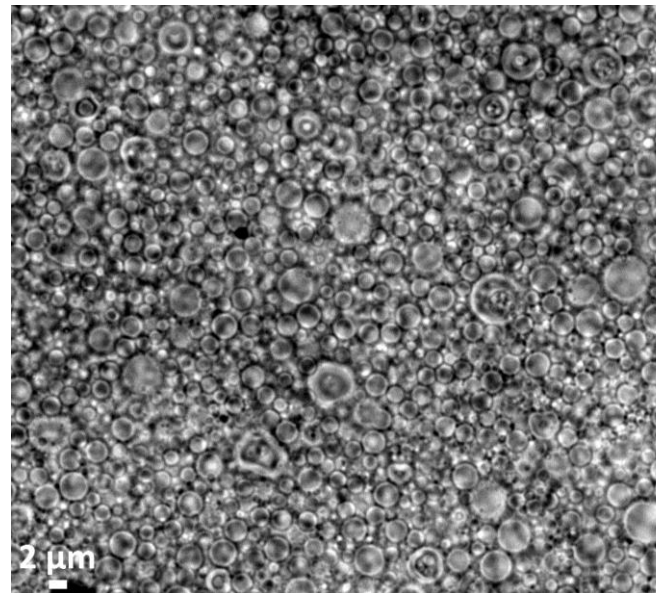


# Biologics - Game changing high drug load subcutaneous delivery (400-500 mg/ml)

Nanoformed monoclonal antibody in dry powder



Nanoformed high drug load monoclonal antibody in non-aqueous suspension



High drug load suspension in a prefilled syringe (400-500mg/ml)



## *Nanoforming enables IV to SubQ switches and multiple injections to a single injection*

- Non-aqueous suspension enables high protein load in a low volume (400-500 mg/ml)
- Intact and stable protein particles in suspension
- Good injectability of suspension with injection force below 20 N using a 27G needle





Q & A

*Nanoform headquarters in Helsinki, Finland*

[www.nanoform.com](http://www.nanoform.com)

*San Diego - Chicago - New York - Lisbon - Manchester - Oxford - London - Cambridge - Bordeaux - Cologne - Stockholm - Budapest - Helsinki - Tokyo*





# APPENDIX

## Selection of upcoming events

<b>May 20-22</b>	<b>CPHI North America, Philadelphia</b>
<b>June 2-4</b>	<b>16<sup>th</sup> Global DDF, Berlin</b>
<b>June 4-5</b>	<b>DCAT Summit, Lugano</b>
<b>June 12</b>	<b>Danske Bank Healthcare Seminar, Helsinki</b>
<b>June 16-19</b>	<b>BIO International, Boston</b>
<b>August 21</b>	<b>Nanoform Q2 2025 report</b>
<b>September 15-16</b>	<b>DDF American Summit, Boston</b>
<b>September 16</b>	<b>Pareto Securities' 16<sup>th</sup> Annual Healthcare Conference 2025, Stockholm</b>
<b>October 27-28</b>	<b>PODD, Boston</b>
<b>October 28-30</b>	<b>CPHI, Frankfurt</b>
<b>November 3-5</b>	<b>Bio Europe, Autumn, Vienna</b>
<b>November 9-12</b>	<b>AAPS PharmaSci 360, Texas</b>
<b>November 20</b>	<b>Nanoform Q3 2025 report</b>
<b>December 10-12</b>	<b>DDL, Edinburgh</b>



# Interesting short videos:

Nanoform high dose subcutaneous delivery of biologics:

<https://nanoform.com/en/nanoform-high-dose-subcutaneous-delivery-of-biologics/>

Discover how Nanoformed API outperform traditional solid dispersions:

<https://nanoform.com/en/nanoform-cphi-milan-2024-tamas-solymosi/>

Nanoform's best-in-class nanodevelopment capabilities:

<https://nanoform.com/en/nanoform-development-capabilities/>

Nanoform's advanced nanoformulation, nanoanalytical, and best-in-class capabilities:

<https://nanoform.com/en/nanoform-formulation-and-analytical-tour/>

Nanoform's state-of-the-art manufacturing capabilities:

<https://nanoform.com/en/nanoform-dr-david-rowe-manufacturing-with-drone/>



# Revenue drivers & industry attrition rates

## Nanoform pre-clinical and clinical revenue drivers

### Non-GMP

#### Proof of Concept (PoC)

- # of active customers
- # of APIs per customer
- Price per PoC per API

#### Proof of Process (PoP)

- Attrition between PoC and PoP
- Price per PoP per API
- Time lag between PoC and PoP

### GMP

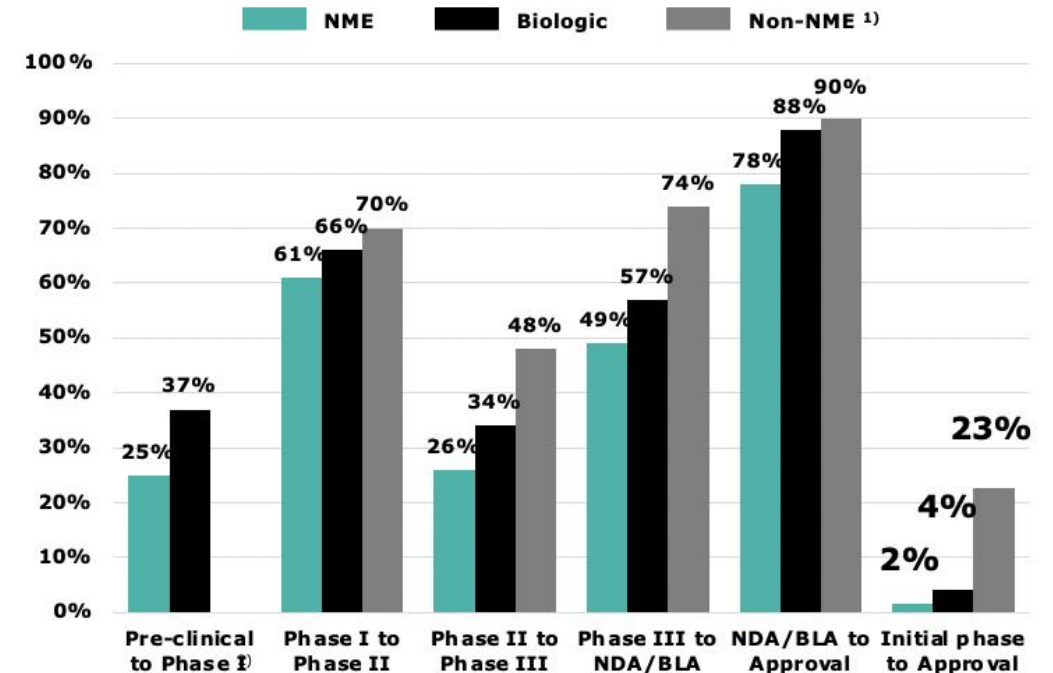
#### Phase I, II & III and/or 505(b)(2)

- Attrition between previous and current phase
- Price per phase per API
- Time lag between previous and current phase
- # of customers with 505(b)(2) strategy
- Proportion of new drug candidates and 505(b)(2) APIs

#### Drugs on the market

- # of drugs on the market using CESS®
- License fee & royalty level per drug
- Net revenues per drug
- Time lag Phase II and market (505b2)
- Time lag Phase III and market
- Speed of uptake on market

## Global Pharmaceutical industry's pre-clinical and clinical success rates



Timeline (years)	Pre-clinical	Phase I	Phase II	Phase III	Approval	Total
New drugs	~1-4	~2	~2	~3-4	~1	~9-13
Existing drugs	-	Clinical development for 505(b)(2) ~2-5			~1	~3-6

# Nanoform Product Kernels

<b>Nanoform internal Product Kernel work</b>	<b>Development partners</b>	<b>Commercial partners</b>
1. Value proposition around a medicine candidate, called 'Product Kernel'	Originator or Supergeneric / High value medicine company	Originator or Supergeneric / High value medicine company
2. New IP that Nanoform owns in an R&D phase	1. Upfront payments 2. Milestones 3. Revenue from Nanoforming the medicine for clinical trials	1. Upfront payments 2. Milestones 3. Revenue from Nanoforming the medicine for clinical trials and commercial phase 4. Royalties/profit share

# Attractive revenue model with pharma and biotech customers

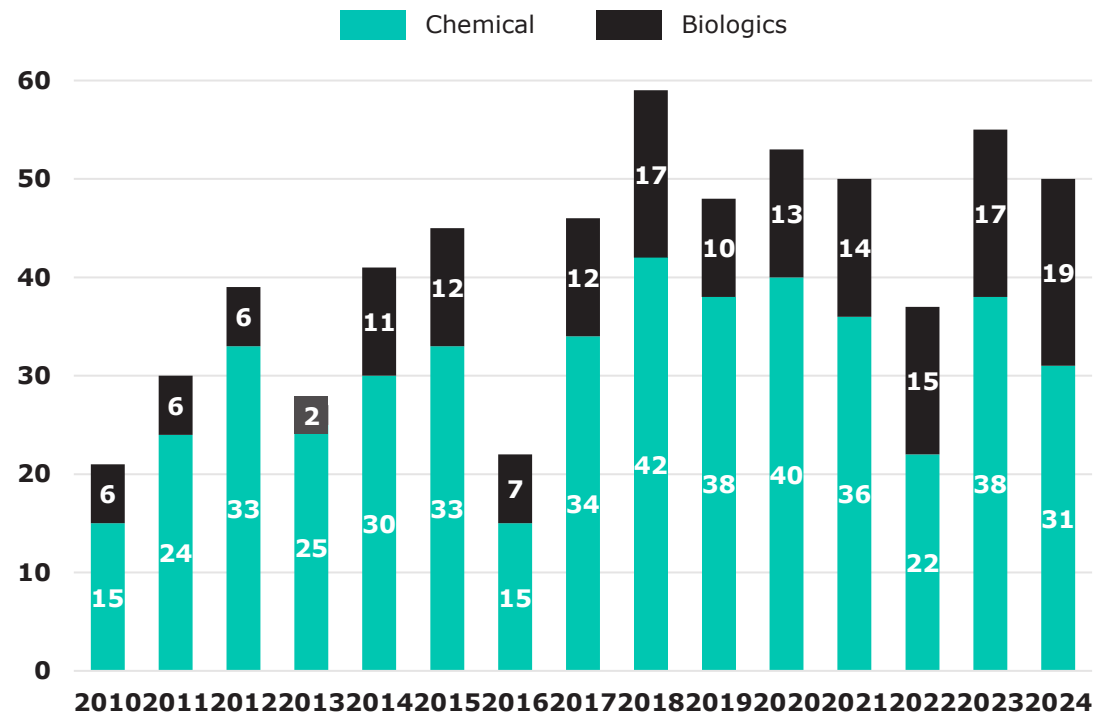
Phase	Proof of Concept / Proof of Process	Phase I – III clinical trials	Drugs on the market
Certification	Non-GMP	GMP	GMP
Description	<ul style="list-style-type: none"> <li>• Proof of concept study - assessment of the possibility to nanoform a specific API</li> <li>• Proof of process study - definition of parameters to establish the optimal process and controls for a specific API</li> </ul>	<ul style="list-style-type: none"> <li>• API for clinical trials are manufactured in Nanoforms GMP facility</li> <li>• Supply of material for customers' Phase I, II and III trials</li> </ul>	<ul style="list-style-type: none"> <li>• Drugs that have passed the trials and reached commercialization</li> <li>• Significant potential from patent extension (505b2 projects) of drugs already on market</li> </ul>
Revenue model	<u>Fixed fee per project</u>  Estimated project fee of EUR 50-500k per API per project	<u>Fixed fee per project</u>  Estimated project fee of EUR 0.5-10m per API per phase	<u>Royalty as a % on drug sales or supply price per kg</u>  Estimated royalty fee of 1-20%



# The structural pharma R&D problem in the pharma industry

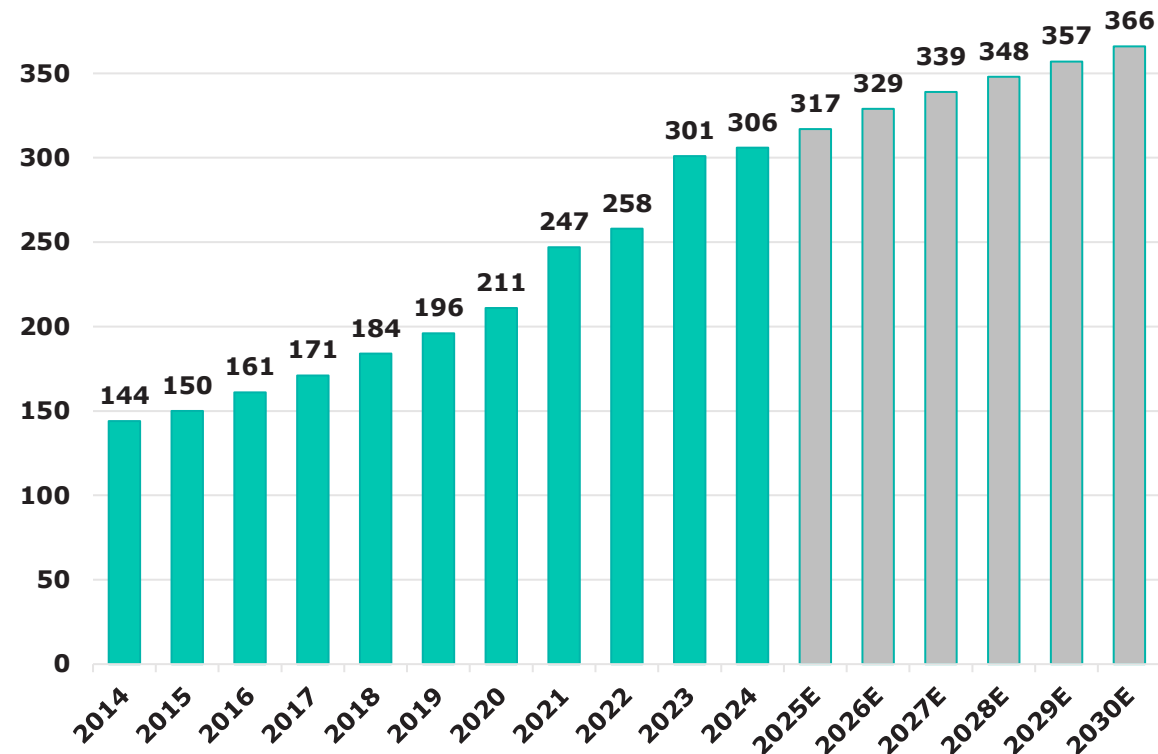
Fewer than 50 drugs approved in the US annually on average...

Annual number of novel drug approvals by FDA 2010-2024



...while the global pharma industry R&D expenditure exceeds \$300B

Global pharmaceutical R&D spending 2014-2030E (USDbn)

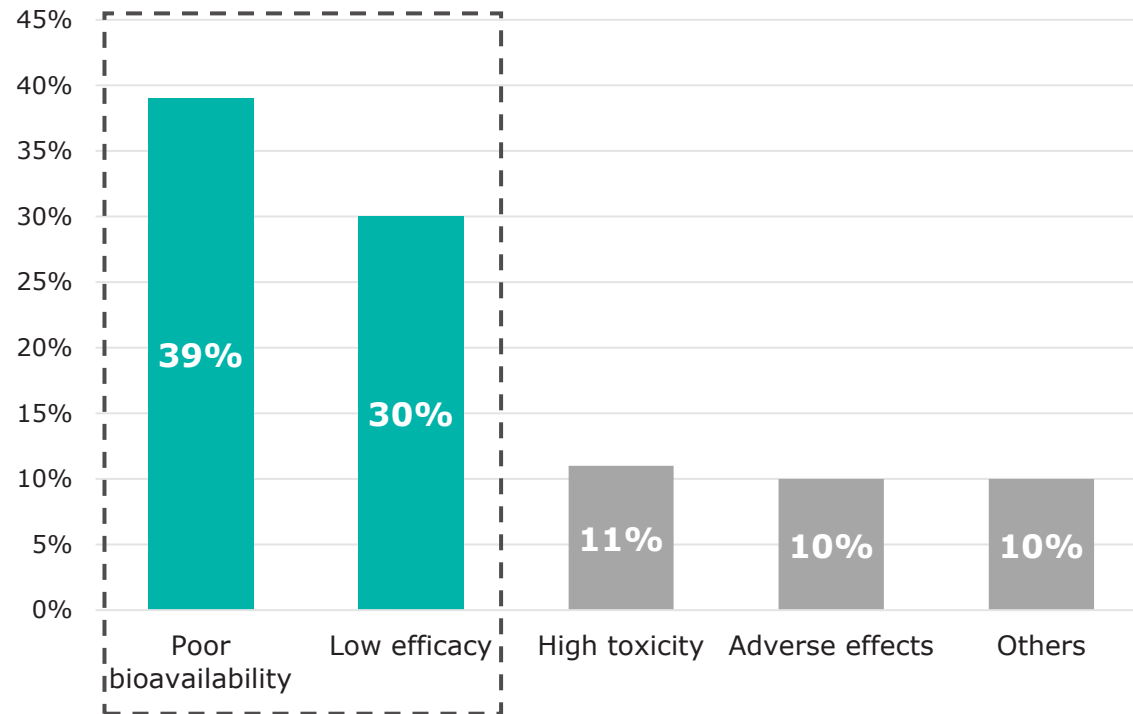


➤ A game changer is needed to improve R&D yield

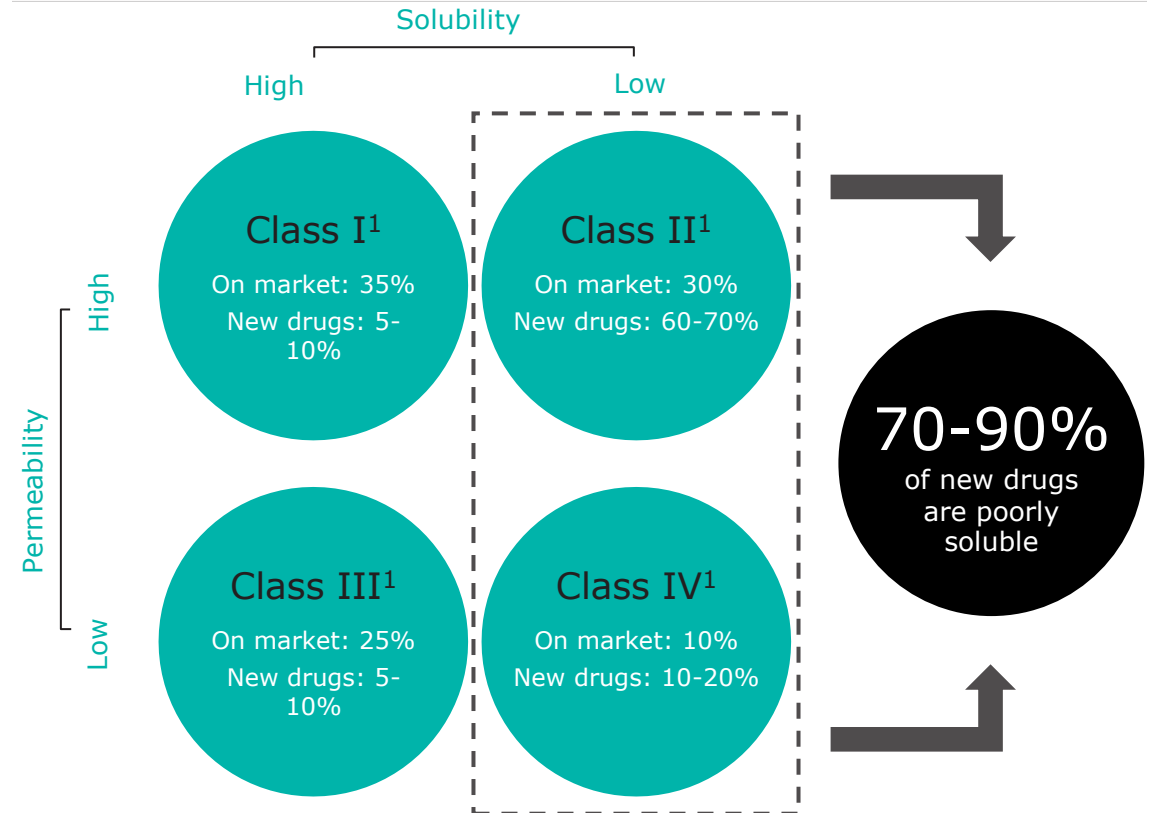
# Low bioavailability is the key issue

## Poor bioavailability and low efficacy most common reasons for drug failure

Reasons for drug failure in pre-clinical trials (share of molecules)



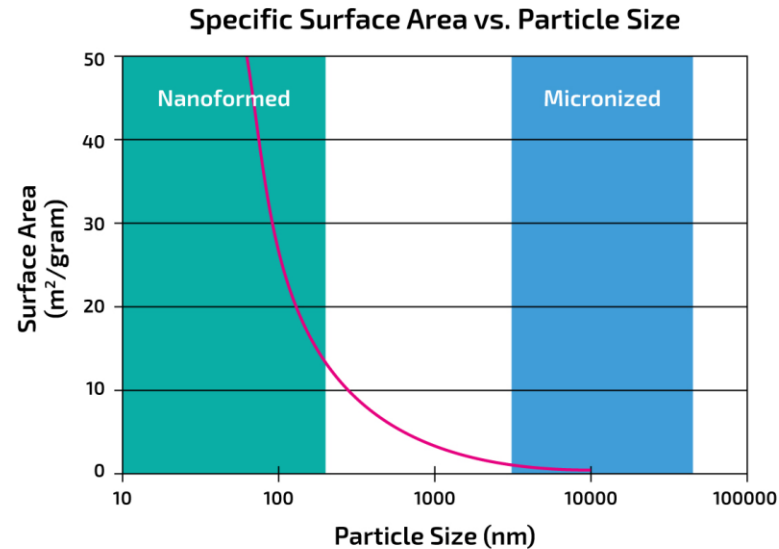
## Majority of new drugs suffer from poor solubility



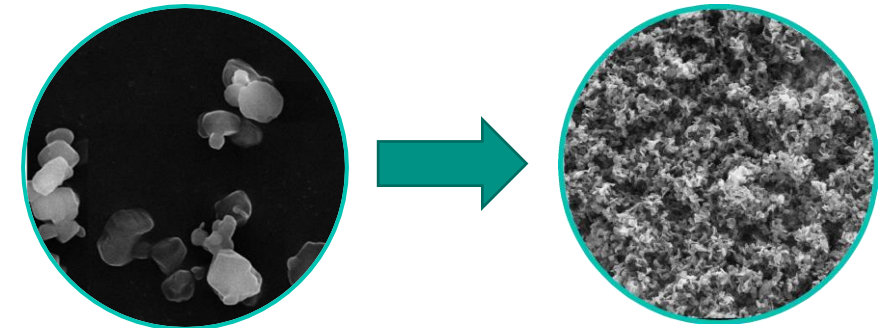
➤ Nanoform can enhance the pharma industry output by targeting poorly soluble drugs

# Particle size is key

## Smaller particle size can improve a drug's bioavailability



- The surface area increases 30-fold from a 10 micron<sup>1</sup> sized particle once the particle size is reduced to 100nm
- Reduction of particle size down to 50nm increases the surface area by 1,000-fold



Pre-nanoforming

Post-nanoforming

- Smaller particles have a larger surface area
- Larger surface area of particles enables improved bioavailability of a drug
- Improved bioavailability implies increased absorption of a drug by the body's circular system
- CESS<sup>®</sup> can produce API with large surface areas which can significantly improve the bioavailability of drugs

➤ CESS<sup>®</sup> produced nanoparticles have a larger surface area and as such improved bioavailability.

# Small molecules - Small is powerful®





# Nanoform is here to fill the gap

Enabling  
new drugs

**> 20,000**  
drugs in  
development\*

Improving  
existing  
drugs

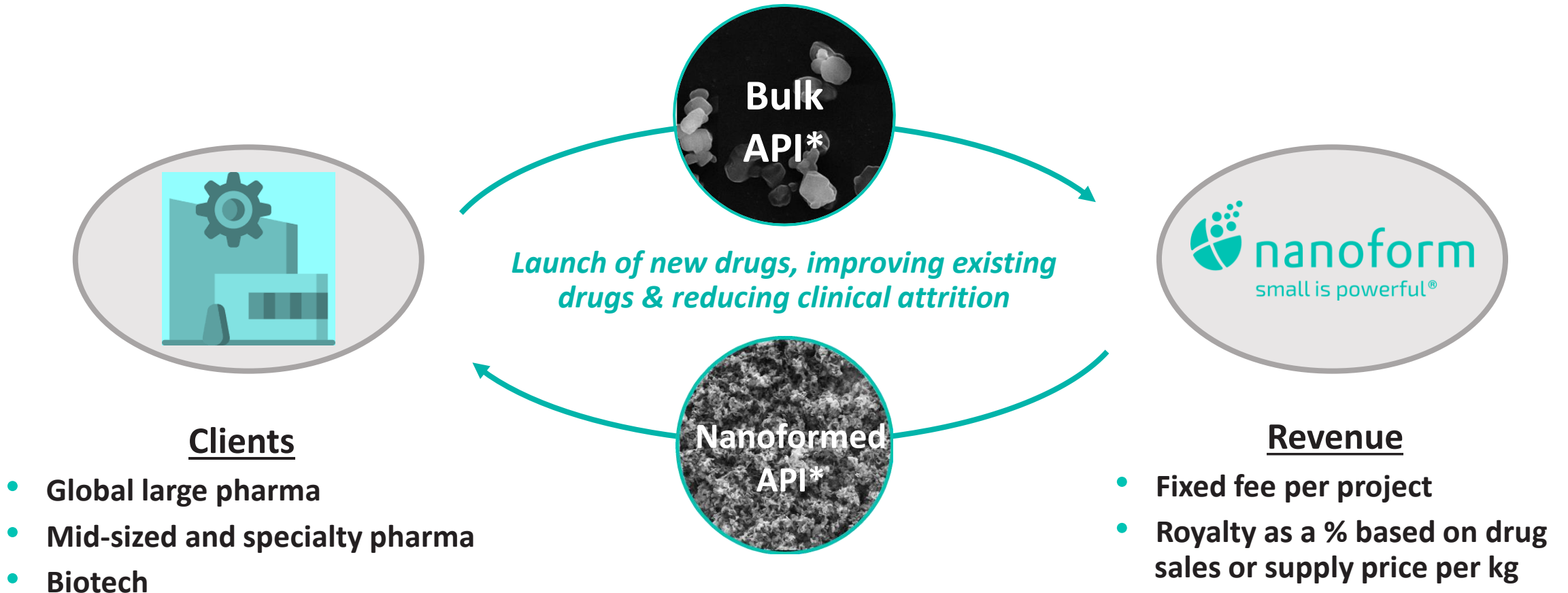
**> 5,800**  
existing drugs\*

Giving  
unsuccessful  
drug candidates a  
second chance

**> 58,000** failed  
drugs in the last 40  
years\*

# Simplified value chain

*High level overview of Nanoform's value chain and business model*



## Growth from IPO 2020 to May 2025

	<i><b>IPO June 2020</b></i>	<i><b>May 2025</b></i>	<i><b>Growth</b></i>
<b>Employees</b>	<b>50</b>	<b>179</b>	<b>~3x</b>
<b>Manufacturing lines</b>	<b>5</b>	<b>20</b>	<b>~4x</b>
<b>Customers enrolled</b>	<b>5</b>	<b>56</b>	<b>~11x</b>
<b>Customer projects started</b>	<b>5</b>	<b>107</b>	<b>~21x</b>
<b>Patents granted</b>	<b>5</b>	<b>30</b>	<b>6x</b>

# Nanoform customer projects – therapy area overview\*

Pre-Clinical	Phase I	Phase II & III	Marketed/505b2
<p><b>Cardiology</b> (e.g. Anemia)</p> <p><b>Gastroenterology</b> (e.g. Microbiome)</p> <p><b>Immunology/Inflammation</b> (e.g. Psoriasis)</p> <p><b>Infectious Disease</b> (e.g. HIV)</p> <p><b>Metabolism and Endocrinology</b> (e.g. Diabetes)</p> <p><b>Neurology</b> (e.g. Parkinsons)</p> <p><b>Oncology</b> (e.g. Multiple Myeloma)</p> <p><b>Ophthalmology</b> (e.g. Glaucoma)</p> <p><b>Respiratory</b> (e.g. COPD)</p>	<p><b>Immunology/Inflammation</b> (e.g. Cystic Fibrosis)</p> <p><b>Dermatology/Oncology</b> (e.g. Basal Cell Carcinoma)</p> <p><b>Neurology</b> (e.g. Parkinsons)</p> <p><b>Oncology</b> (e.g. Solid Tumors)</p> <p><b>Ophthalmology</b> (e.g. Cataract)</p> <p><b>Pain</b> (e.g. Post Operative Pain)</p> <p><b>Infectious Disease</b> (e.g. HIV)</p>	<p><b>Metabolism and Endocrinology</b> (e.g. Adrenal Hyperplasia)</p> <p><b>Neurology</b> (e.g. Schizophrenia)</p> <p><b>Oncology</b> (e.g. lung cancer)</p>	<p><b>Infectious Disease</b> (e.g. HIV)</p> <p><b>Immunology/Inflammation</b> (e.g. HEP B)</p> <p><b>Immunology/Inflammation )</b> (e.g. Cystic Fibrosis)</p> <p><b>Oncology</b> (e.g. Prostate Cancer)</p> <p><b>Ophthalmology</b> (e.g. Glaucoma)</p>



# Nanoform has made substantial progress in Nanoforming solutions with in-vitro, in-vivo, and clinical study results

## Oncology:

Replaced amorphous solid dispersion (ASD) formulations with nanocrystalline high drug load formulations, matching bioequivalence for Enzalutamide and Apalutamide where life cycle management **opportunities to reduce tablet burden to a single, smaller, easier-to-swallow tablet** as well as working on Aprepitant in partnership with PlusVitech for lung cancer to develop a regimen with substantially fewer tablets.

## Inhalation:

Engineering nanoformulations of both small and large molecules with excellent fine-particle dose (FPD) and fine-particle fraction (FPF) performance in comparison to spray drying technologies. In biologics, Nanoform has shown FPF >95% vs 50% with spray drying for delivering **high drug load** to the lungs.

## Biologics:

Demonstrated in partnership, with Takeda and other companies, **ultra-high concentrations for subcutaneous drug delivery** with acceptable viscosity for injection (Takeda – Plasma Derived Therapies).

## Ophthalmic:

Multiple projects where nanoparticles have shown improved delivery potential. **High drug load** to the eye enabling smaller implants with no requirement for mesh membranes, eye drop suspensions and ophthalmic inserts.

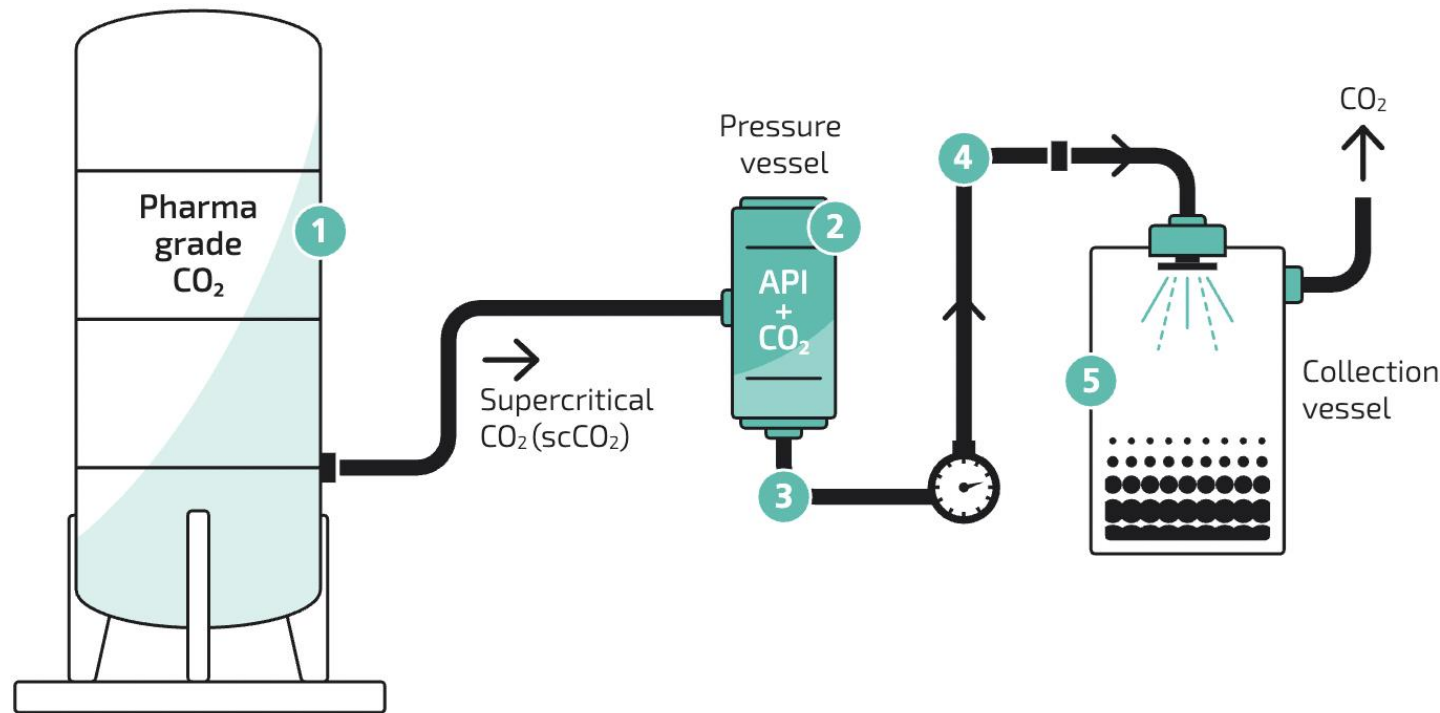
## Hydrogels:

Shown **high drug load** applications (5 x more than nanomilling) for post-surgical glioblastoma drug delivery and deep penetration across the brain parenchyma **enabling non-recurrence of glioblastoma** where other formulations failed.

## IP:

**Novel technologies, processes and formulations** can enable market opportunities, lifecycle management and strong launch strategies

## Controlled Expansion of Supercritical Solutions - CESS<sup>®</sup>



- 1 Supercritical CO<sub>2</sub> is guided into a pressure vessel loaded with API
- 2 Increasing the pressure and temperature in the vessel dissolves the API in supercritical CO<sub>2</sub>
- 3 The CO<sub>2</sub> and the API are released from the pressure vessel and the flow, pressure and temperature profiles are accurately controlled
- 4 The pressure and temperature is controlled to achieve a stable nucleation phase and formation of nanoparticles
- 5 In a collection vessel the CO<sub>2</sub> is sublimated resulting in final nanoparticles ready for collection and formulation

➤ Relatively simple process developed through combining deep knowledge in physics, chemistry, and pharma

# CESS® Superior to Existing Technologies

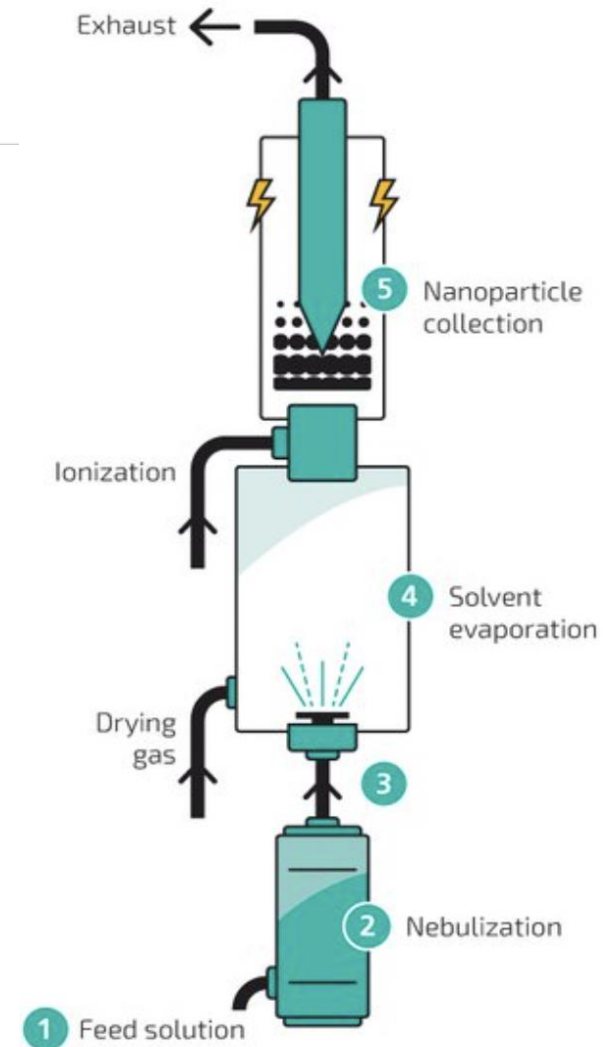
	Controlled Expansion of Supercritical Solutions (CESS®)	Solid dispersion (e.g. spray drying)	Jet milling	Nanomilling
Description	Extracts API from supercritical CO <sub>2</sub> by applying controlled reduction in pressure	API is dispersed into a solid material, which dissolves when exposed to an aqueous media	Application of energy to physically break down API particles to finer ones	API particle size is reduced in a liquid vehicle via grinding
Particle size	Down to 10nm	300nm-25µm	800nm-10µm	>150nm
Particle formation	Controlled crystalline or amorphous and stable	Amorphous (unstable without excipients)	Unstable (crystalline and amorphous structures)	Unstable (crystalline and amorphous – needs excipient to stabilise)
Ease of formulation	✓	✗	✗	✗
Reproducibility	✓	✓	✗	✗
Free from excipients and solvents	✓	✗	✓	✗
Yield	High	Low	High	Low
Investment	Low	High	Low	Low

# Large molecules - Proprietary technology

Green  
technology

## Nanoforming process for biologics

- 1 API containing feed solution is pumped into the nebulizer
- 2 Feed solution is nebulized into a carrier gas
- 3 Mist is transported into the drying chamber via a connection pipe
- 4 Mist is dried using low-temperature drying gas
- 5 Dried particles are charged by the ionizer and collected using electrostatic precipitation

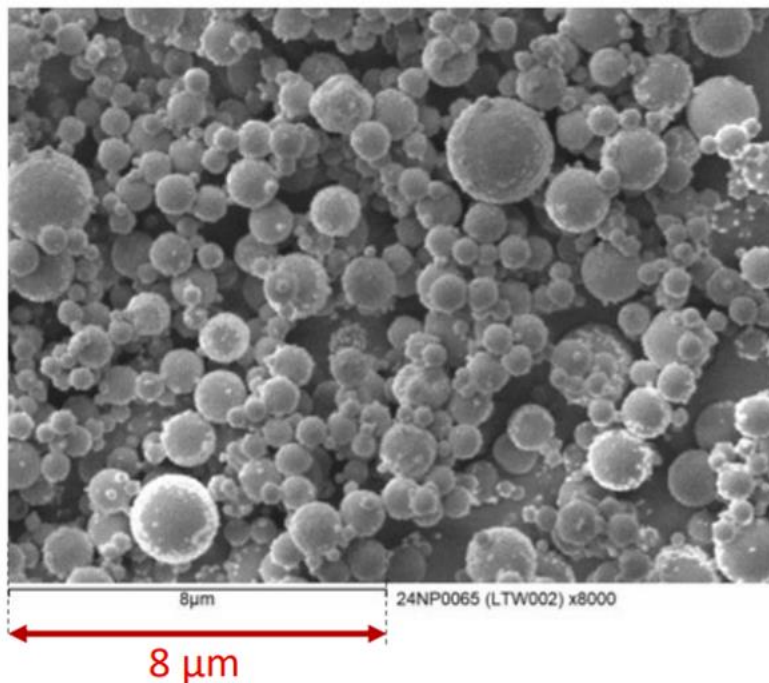




# Comparison of Nanoform's proprietary biologics technology vs existing technologies

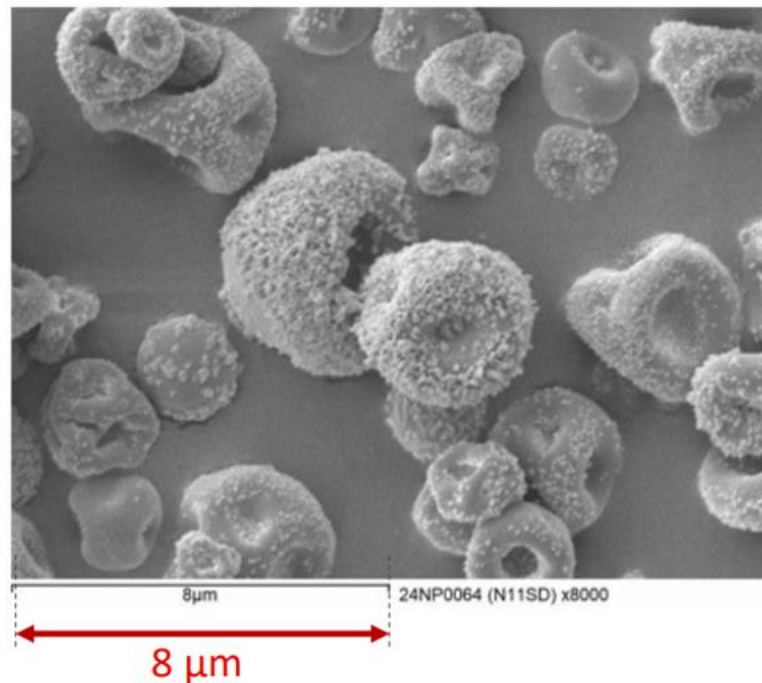
## Nanoformed

Perfect spheres, highly flowable and aerodynamic, great packing and injection properties



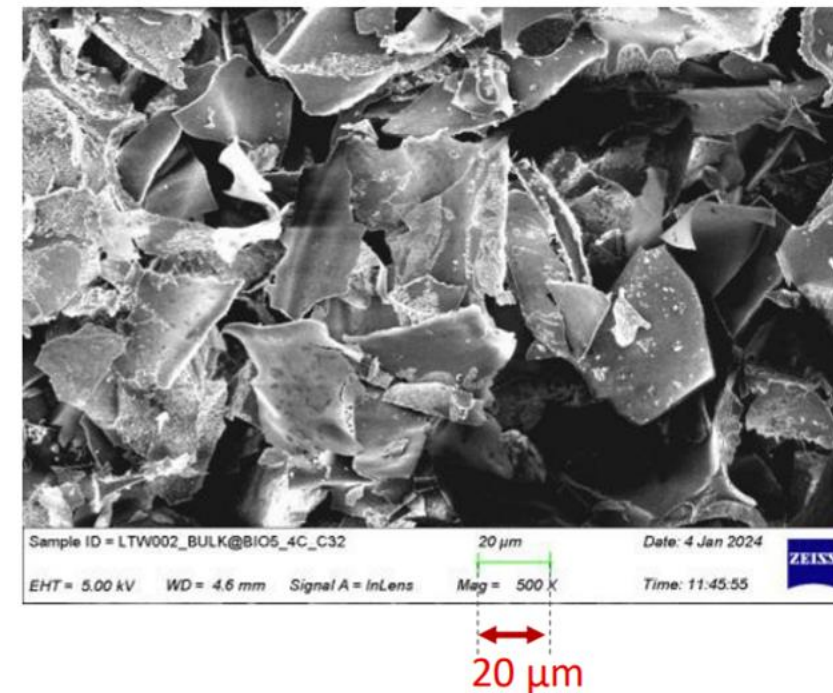
## Spray dried

Sticky, poor flowability, raisin shaped



## Lyophilized / freeze dried

Flaky morphology, dry cake, no flowability



Nanoforming biologics: Superior flowability, aerodynamic performance, high density packing, lower injection force properties, improved material quality and stability properties vs spray drying and lyophilization

# Business case Amorphous Solid Dispersions (ASDs)

Amorphous solid dispersion (ASD) medicines are currently the leading formulation strategy for poorly soluble APIs and there are ~50 marketed medicines globally that are ASDs and sell for ~\$50bln annually

Nanoformed and nanocrystalline medicines (e.g. nanoenzalutamide etc) offer an attractive alternative to ASD medicines (and other) with the following benefits to originators and supgeneric/high value medicines companies:

- *green manufacturing process*
- *substantially higher drug load in the final drug product*
- *reduced pill burden for the patient*
- *opportunity to extend IP protection for the reformulated and improved product*
- *opportunity for earlier market entry*
- *possibility for fixed dose combinations*

# Nanoenzalutamide clinical trials

## 2023-2024

Phase 1/Pilot clinical trial in North America.

**Relative bioavailability study** of nanocrystalline-enabled enzalutamide (nanoenzalutamide) tablet formulation, an alternative to the amorphous solid dispersion (ASD) used in Xtandi®.

The single-dose, randomized, comparative bioavailability study, which was performed by a contract research organization (CRO) in North America and completed on January 25, 2024, compared enzalutamide 160mg filmcoated tablets (Bluepharma) and Xtandi® 4×40 mg film-coated tablets (Astellas Pharma Europe B.V.).

The **clinical trial demonstrated promising results.**

## 2025

**Pivotal bioequivalence clinical trials** in EU and US are expected to start in Q2 2025, with first read-outs in the summer of 2025.

Bioequivalence means 80% - 125% of the Cmax and AUC in a **large cohort study in fed and fasted states** with a 90% confidence interval.

Nanoenzalutamide is expected to progress via the ANDA (Abbreviated New Drug Application)/Hybrid generic pathway and as such will need **to show bioequivalence vs the originator product, Xtandi®.**

License and commercial supply agreements are expected to be signed shortly.

We plan nanoenzalutamide to take a meaningful share of this market through its highly **patient centric product differentiation** (1 tablets 4 tablets) and **unique IP position** (different technology, crystalline product, different excipients), while not forgetting its **green attributes.**

# Project Nanoenzalutamide (oral tablet for prostate cancer)

**Clinical results 26.1.2024:** Very promising relative bioavailability study of nanocrystalline-enabled enzalutamide\* (nanoenzalutamide) tablet formulation.

**Nanoforming benefits:** 1) Opportunity for an improved and differentiated finished product, 2) Development of a 160mg, single tablet per day regimen may be preferable for patients in need of reducing their total number of daily pills 3) Unique IP position may allow the nanoenzalutamide product to enter the market prior to other generic competition based on the ASD formulation, which is currently patent protected in the US and Europe until 2033

**Next steps:** Manufacture Nanoformed material for registration batches and EU/US **pivotal bioequivalence clinical trials that are expected to start in Q2 2025**, with first read-outs in summer of 2025. **License and commercial supply agreements are expected to be signed in coming quarters.**

**Target launch:** Submissions of dossiers 1H 2026, launch after expiry of the enzalutamide substance patent in USA 2027 & in Europe in 2028. Nanoenzalutamide is expected to progress via the ANDA (Abbreviated New Drug Application)/Hybrid generic pathway and as such will need to show bioequivalence vs the originator product, Xtandi®. In the eyes of the regulators, bioequivalence typically means 80% - 125% of the Cmax and AUC in a large cohort study in fed and fasted states with a 90% confidence interval. The global annual sales of Xtandi® is presently USD 6bn and growing. We plan nanoenzalutamide to take a meaningful share of this market through its highly patient centric product differentiation (1 tablets 4 tablets) and unique IP position (different technology, crystalline product, different excipients), while not forgetting its green attributes. We expect nanoenzalutamide to be the first nanoformed medicine to reach the market.

**Value added medicine companies vs originators:** We see the program to be attractive to value added medicine companies as a uniquely differentiated and high value supergeneric product that can enable a product launch before market entry by other generic products based on the ASD formulation, for which the originator currently holds patents in both Europe and the US (with expiry dates in 2033). For the originator company we believe that the nanocrystalline single tablet product offers a patient centric life cycle extension opportunity with compelling sustainability advantages that would be difficult for generic competitors to match. Avoiding the inherent stability challenges associated with amorphous materials is also a clear benefit for any company considering alternative formulation approaches.



# Project Nanoapalutamide (oral tablet for prostate cancer)

**FEBRUARY 19, 2024 – APALUTAMIDE STUDY AGAIN DEMONSTRATES THE ADVANTAGES OF NANOFORMING OVER TRADITIONAL CANCER TREATMENT FORMULATIONS**

**Positive results from own pre-clinical, in-vivo study of a nanocrystalline-enabled apalutamide oral formulation, which shows potential to enable a much smaller tablet than Erleada<sup>®</sup>,** (Erleada is a registered trademark for Apalutamide owned by Johnson & Johnson / Janssen Biotech, Inc.) a nonsteroidal antiandrogen (NSAA) blockbuster amorphous solid dispersion (ASD) medicine used to treat prostate cancer. The nanocrystalline-enabled formulation provided high serum concentration (Cmax), fast time to peak drug concentration (Tmax), and 100% absolute bioavailability.

Nanoform's nanocrystalline formulations enable significantly higher drug loading, allowing for smaller pills and a reduced pill burden. Its technology is free from organic hydrocarbon solvents, offering an environmentally sustainable alternative.

**NOVEMBER 18, 2024 – PROJECT NANOAPALUTAMIDE PROGRESSING ACCORDING TO PLAN**

We were pleased with the **positive results from a recent in vivo study** comparing Nanoform's tablet prototypes with the currently marketed product. The results provide confidence in our choice of the lead tablet prototypes and are expected to further accelerate interest among potential partners. Based on earlier experience with Nanoenzalutamide, we expect that following further optimization of the formulation, the **next major development milestone for this project is a pilot PK study in humans during H2 2025.**

# Takeda (plasma-derived formulations for rare conditions)

MAY 7, 2024 - NANOFORMED HIGH-CONCENTRATION BIOLOGICS FORMULATION FOR SUBCUTANEOUS DELIVERY RESULTS TO BE PRESENTED BY TAKEDA AT DDF SUMMIT

The proof-of-concept study data support the potential of Nanoform's patented biologics platform to achieve high protein concentrations in suspension formulations that are suitable for subcutaneous injection, as shown by results of syringeability and injectability studies.

Controlling the viscosity and aggregation of protein-based solutions is important for pharmaceutical formulators. Because injection volume is limited by the device, therapeutic protein formulations which are to be delivered via intramuscular or intravenous injection need to be highly concentrated. At protein concentrations greater than 200 mg\*mL<sup>-1</sup> however, viscosity increases to significantly higher than 20 cP (centipoise) to quickly exceed the maximum 40 cP viscosity deemed acceptable for a conventional subcutaneous injection.

AUG 15, 2024 - NANOFORM COLLABORATES WITH TAKEDA ON THEIR PLASMA-DERIVED THERAPY DEVELOPMENT

Nanoform enter into a pre-clinical development agreement with the Plasma-derived Therapies Business Unit of Takeda Pharmaceuticals Inc. to develop innovative plasma-derived therapy formulations for the treatment of rare conditions. Following the completion of in vitro proof of concept studies of a novel plasma-derived therapy formulation, Nanoform will provide non-GMP nanomaterial to Takeda for in vivo studies. The first results of these studies are expected in Q2 2025. It is the intention of both Nanoform and Takeda to develop medicine candidates to clinic and then take them as products to the market.

Nanoform Biologics' nanoforming technology can deliver large-molecule drug particles of tuneable size and morphology, while retaining biological activity. The technology can be applied across the biologics field, from 1 to 150KDa, to enable novel routes of delivery, enhance drug loading, tailor release profiles and engineer new drug combinations.

# Project Glioblastoma (hydrogel for central nervous system cancer)

Nanoform customer TargTex S.A. was granted **Orphan Drug Designation** by FDA for its nanoformed drug candidate TTX101 to be used in patients with malignant gliomas (October 2023). The orphan drug designation follows the generation of a preclinical rodent data package in which a **survival advantage** was shown for this nanoform-enabled medicine candidate.

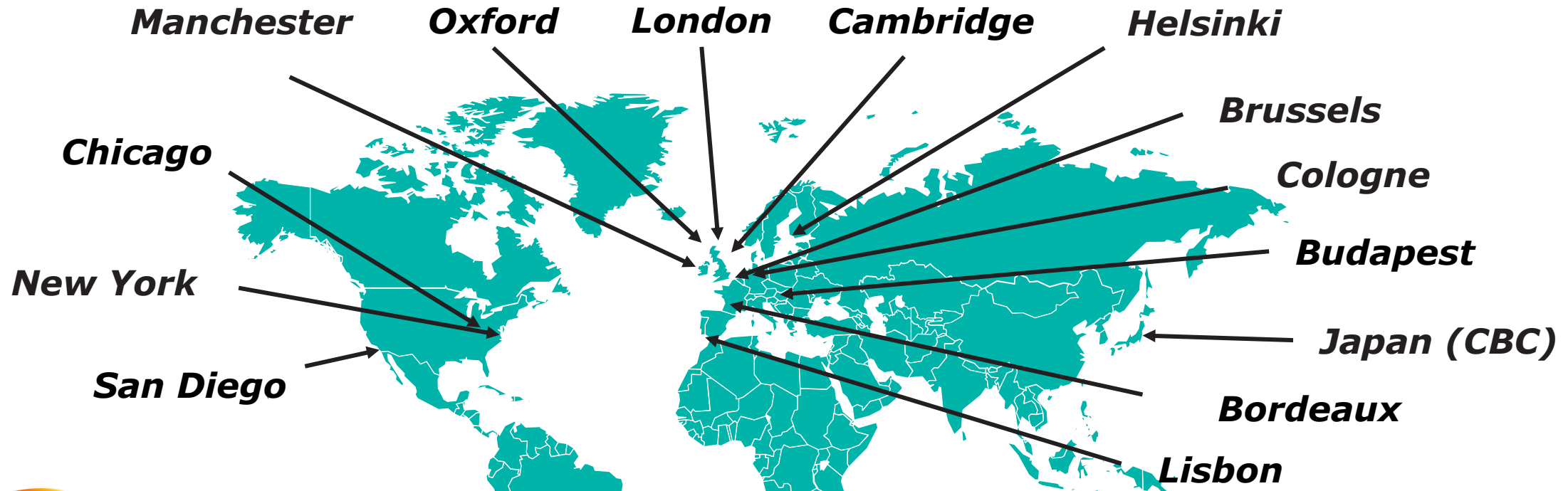
The hydrogel **nanoformulation developed by Nanoform enabled a 200-fold increase** in drug load compared to bulk and a 5-fold increase in drug load compared to nanomilling.

In November 2023, the **European Innovation Council and SMEs Executive Agency (EISMEA)** awarded **TargTex €14m in funding**.

TargTex is currently raising additional funds to take this innovative treatment to clinic and is planning a phase 1/2a **clinical trial in recurrent glioblastoma (GBM) patients across the US and EU**, in which nanoformed TTX101 is applied as adjunct to surgery after tumour excision.

# Experienced global sales team driving commercialization

– Locations and previous experiences





# Management team: Multi-disciplinary with international merits



**CEO & Co-founder; Ph.D. (Applied physics), MBA**

**Edward Hæggström**

- Professor at the University of Helsinki, Head of Electronics Research Lab. within the Dept. of Physics
- Previously visiting professor at Harvard Medical School, visiting scholar at Stanford University and project leader at CERN
- Has led large number of scientific projects
- *Current ownership: 5,409,405 shares and 204,000 options*



**CCO; M.Sc. (Chemistry)**

**Christian Jones**

- Previously Commercial Director and member of the Senior Leadership Team for the Global Health Sector at Johnson Matthey
- Senior roles at Dr. Reddy's Global Custom Pharma Solutions and Prosonix
- **Key area of responsibility:** Commercial strategy and business development
- *Current ownership: 384,000 options*



**General Counsel & Chief Development Officer; LL.M**

**Peter Hänninen**

- Previously Attorney, Borenus Attorneys
- Successful track-record of advising technology companies from founding to exit in key transactions and collaborations
- **Key area of Responsibility:** Legal, Compliance, IPR, HR, IT
- *Current ownership: 133,125 shares and 530,000 options*



**Chief Quality Officer, M.Sc. (Pharmacology)**

**Johanna Kause**

- Previously Head of Quality, Regulatory and Safety for Finland and the Baltics at Takeda Pharmaceuticals
- 25 years of experience in Quality Management in the Pharma sector
- **Key area of responsibility:** Quality Management, GMP, GDP
- *Current ownership: 130,000 options*



**CFO and member of the Board; B.Sc. (Economics)**

**Albert Hæggström**

- 20 years of finance and investing experience
- Prior roles include positions at Alfred Berg, BNP Paribas, Nordea and SEB
- *Current ownership: 749,275 shares and 670,000 options*



**Head of Manufacturing; Ph.D. (Chemistry)**

**David Rowe**

- Previously Particle Size Reduction Lead for GlaxoSmithKline
- Chaired the PSR Centre of Excellence
- **Key area of responsibility:** Technical leadership within new chemical entities and commercial assets
- *Current ownership: 413,720 options*



**Chief of Business Operations (Chemistry and Quality)**

**Antonio da Silva**

- Degree in Chemistry from Lisbon University and Master degree in Quality from the University Aberta of Lisbon
- Extensive background in the CDMO and particle engineering space (19 years at Hovione)
- **Key area of responsibility:** Pharmaceutical product launches
- *Current ownership: 24,500 shares and 224,516 options*



# Board of directors: Top executives from leading industry positions



## Miguel Calado

### Chairman of the Board

- Previously CFO at international particle engineering CDMO company Hovione Group
- Other previous roles include CFO at PepsiCo International and President International Operations at Dean Foods
- Experienced Board member in both the EU and the US
- *Current ownership: 101,386 shares and 380,000 options*
- **Key experience:**



PEPSICO



## Albert Hæggström

### CFO and Board Member

- 20 years of finance and investing experience
- Prior roles include positions at Alfred Berg, BNP Paribas, Nordea and SEB
- *Current ownership: 749,275 shares and 670,000 options*
- **Key experience:**



## Jeanne Thoma

### Board Member

- 30+ years of experience in global pharmaceutical and life science leadership
- Prior roles include executive positions at BASF Inc, Lonza AG and SPI Pharmaceuticals
- *Current ownership: 50,308 shares and 38,630 options*
- **Key experience:**



We create chemistry





## FURTHER ENQUIRIES

CEO Edward Hæggström - [edward.haeggstrom@nanoform.com](mailto:edward.haeggstrom@nanoform.com), +358 50 317 54 93

CFO Albert Hæggström - [albert.haeggstrom@nanoform.com](mailto:albert.haeggstrom@nanoform.com), +358 40 161 4191

DIR Henri von Haartman - [hvh@nanoform.com](mailto:hvh@nanoform.com), +46 76866 50 11